122). In exchange for this pre-issue public disclosure, the AIPA also provided a provisional right under 35 U.S.C. 154(d) to obtain a reasonable royalty if the invention as claimed in the published patent application is substantially identical to the invention claimed in any patent that might issue therefrom, and certain other conditions are met.

In amending 35 U.S.C. 122, Congress made it clear that only those patent application publications which provide an enabling disclosure of the claimed invention would be entitled to provisional rights under 35 U.S.C. 154(d). Although the AIPA allowed for certain applications to be published in redacted form, any redacted application was nevertheless required to contain a disclosure that would allow a person skilled in the art to make and use the subject matter of the claim. ''The provisions of section 154(d) shall not apply to a claim if the description of the invention published in the redacted application filed under this clause with respect to the claim does not enable a person skilled in the art to make and use the subject matter of the claim.'' 35 U.S.C. 122(b)(2)(B)(v). By allowing for provisional rights only where the patent publication contains an enabling disclosure, Congress again reinforced the notion that exchange for the rights associated with a patent grant an inventor must disclose his invention in such a manner that would allow the public to make and use it without undue experimentation.

When an invention involves biological material, sometimes words and drawings alone cannot sufficiently describe how to make and use it. As a supplement to the printed written description of an invention, courts have sanctioned a procedure in which biological material may be deposited with an appropriate holding facility under conditions which ensure that the sample is properly maintained, and made available to others when appropriate.

For biological inventions, for which providing a description in written form is not practicable, one may nevertheless comply with the written description requirement by publicly depositing the biological material * * *. Such description is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.

*Enzo Biochem, Inc.* v. *Gen-Probe, Inc.,* 323 F.3d 956, 970, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Internationally, the deposit of biological materials is governed by the Budapest Treaty.

The proposed rule change brings the Office practice regarding biological deposits in line with the publication of patent applications under AIPA. Courts have consistently recognized that an applicant must have provided the Office with an enabling disclosure no later than the time an invention is disclosed to the public. Prior to publication of patent applications under the AIPA, disclosure occurred simultaneously with patent issuance. Thus, earlier court decisions held that deposits needed to be perfected at the time the patent became public, i.e., at the issue date. For example, in *In re Hawkins* the court stated that ''the function of section 112 in ensuring complete public disclosure is only violated if the disclosure is not complete at the time it is made public, i.e., at the issue date.'' *In re Hawkins,* 486 F.2d 569, 574, 179 USPQ 157, 161 (CCPA 1973). In *In re Argoudelis,* the court specifically referred to the regulation concerning conditions for making a patent application public, 37 CFR 1.14, when it stated, ''The cultures are to be made available to the public upon issuance of a United States patent which refers to such deposit and prior to issuance of said patent under the conditions specified in Rule 14.'' *In re Argoudelis,* 434 F.2d 1390, 1393, 168 USPQ 99, 102 (CCPA 1970).

In the era since *Hawkins* and *Argoudelis* were decided, Congress changed the law to require that most patent applications be published eighteen months after filing, and to grant provisional rights under certain conditions. Publication of patent applications under the AIPA means that the patent issue date is no longer ''the time [the patent disclosure] is made public,'' or the time when ''the conditions of Rule 14 are met.'' At least one commentator has stated that a result of the changes brought about by the AIPA is that there is now a requirement for release of a biological deposit at publication. *See* Michelle Henderson, ''International Harmonization Brought about by the American Inventors Protection Act Compels Early Release of the Biological Deposit,'' 42 IDEA: The Journal of Law and Technology 361 (2002).

In a more recent case involving enablement supported by a biological deposit, the Federal Circuit held that ''the availability of a sample to the public after the patent has issued will meet the enablement requirement.'' *In re Lundak,* 773 F.2d 1216, 1223, 227 USPQ 90, 95 (Fed. Cir. 1985). Although on its face *Lundak* might seem to support delaying public access to a deposit until issue, *Lundak* was decided before provisional rights under the AIPA were instituted. Like the decisions in *Argoudelis* and *Hawkins,* the rule established in *Lundak* is superseded by the AIPA.

The Office did not implement a rule change requiring unrestricted access to biological deposits referenced in published patent applications at the time the patent application publication rules were put in place because a report to Congress required by the AIPA was still pending at that time. Section 4805 of the AIPA required that the Comptroller General (in consultation with the Office) conduct a study and submit a report to Congress on the potential risks to the biotechnology industry in the United States relating to release of biological material deposited in support of biotechnology patents, and that the Office consider the recommendations of such study in drafting regulations affecting deposits of biological material (including any modification of § 1.801 *et seq.*). The study required by Section 4805 of the AIPA was completed in October of 2000. *See Deposits of Biological Materials in Support of Certain Patent Applications,* GAO–01–49 (Oct. 2000). This report may be obtained: (1) By mail addressed to the Government Accountability Office, 441 G Street, NW., Washington, DC 20548; (2) by telephone at (202) 512–6000, facsimile at (202) 512–6061, or TDD (202) 512–2537; or (3) via the Government Accountability Office's Internet Web site at *http://www.gao.gov.*

The Office had previously proposed changes to § 1.809 in order to reduce delays after allowance of a patent application. *See Changes to Implement the Patent Business Goals,* 64 FR 53771 (Oct. 4, 1999), 1228 *Off. Gaz. Pat. Office* 15 (Nov. 2, 1999) (proposed rule). The GAO study did not contain any recommendations related to the Office's proposal to amend § 1.809 to revise the time period within which a deposit of biological material (if needed) must be made after allowance of an application. Accordingly, the Office has already amended § 1.809 to provide that the period of time within which the deposit must be made in order to avoid abandonment is not extendable under § 1.136(a) or (b) if set forth in a ''Notice of Allowability'' or in an Office action having a mail date on or after the mail date of a ''Notice of Allowability.'' *See Changes to the Time Period for Making any Necessary Deposit of Biological Material,* 66 FR 21090 (April 27, 2001), 1246 *Off. Gaz. Patent Office* 42 (May 22, 2001) (final rule).

As to release of the deposit before issuance of the application, the GAO study noted the concern of the